JUL - 7 2000

K001371

APPENDIX G

510(k) SUMMARY

510(k) number: _____

This summary of information is being provided in accordance with 21 CFR 807.92(a).

Applicant Information:	Cardeon Corporation 10161 Bubb Road Cupertino, CA 95014
Contact Person:	Jane Beggs Regulatory Affairs Cardeon Corporation
Date Summary Prepared:	28 April 2000
Device Trade Name:	Cardeon® Ascending Balloon Cannula (ABC™)
Device Common Name Regulation No.:	Catheter, cannula and tubing, vascular, cardiopulmonary bypass 870.4210
Classification / Code:	Class II / DWF

Indications for Use: The Cardeon® Ascending Balloon Cannula is intended to perfuse the aorta during open chest (sternotomy) procedures on cardiopulmonary bypass and isolate the myocardium and aortic root. The ABC also allows delivery of antegrade cardioplegia and venting of the aortic root.

Summary of Substantial Equivalence: The Ascending Balloon Cannula is substantially equivalent to currently marketed devices used to directly cannulate and perfuse from a general cardiac surgery patients undergoing coronary artery bypass grafting or valve replacement and/or repairs on CPB via sternotomy. Aortic occlusion is achieved by the fluid inflation of an integrated balloon thereby preventing the backflow of blood into the surgical field. Additional lumens allow delivery of antegrade cardioplegia or venting of the aortic root. The subject and predicate devices use standard attachments for connection(s) to cardiopulmonary bypass circuit. Substantial equivalence is supported through comparison with several marketed devices with the same indications for use, including arterial cannulae integral occlusive balloon and external cross clamps. Differences between the Ascending Balloon Cannula and other devices do not raise any new issues of safety and effectiveness.

Based on comparisons to currently marketed devices and performance testing of the subject device, the Cardeon Ascending Balloon Cannula is substantially equivalent to predicate devices with regard to intended use, indications for use, device performance and technological characteristics.

Product Testing: The determination of substantial equivalence was also based on an assessment of device biocompatibility, in vitro and in vivo performance. Results of product testing demonstrated that the Ascending Balloon Cannula functions as safely and effectively as predicate arterial return cannulae and aortic occlusive balloons.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2000

Jane Beggs
Director of Regulatory Affairs
Cardeon
10161 Bubb Road
Cupertino, CA 95014

Re: K001371
Cardeon® Ascending Balloon Cannula (ABC™)
Regulatory Class: II (two)
Product Code: DWF
Dated: April 28, 2000
Received: May 1, 2000

Dear Ms. Beggs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001371

Device Name: Cardeon® Ascending Balloon Cannula (ABC™)

Indications for Use:

The Cardeon Ascending Balloon Cannula is intended to perfuse the aorta during open chest (sternotomy) procedures on cardiopulmonary bypass up to 6 hours or less. The ascending balloon isolates the myocardium and aortic root when inflated. The ABC also allows delivery of antegrade cardioplegia and venting of the aortic root.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the Counter Use ______

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number K001371